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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/017,524	02/03/1998	RALPH T. KUBO	018623-00509	8468

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	36

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/017,524	KUBO ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2003 and 09 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-64 and 68-94* is/are pending in the application.

4a) Of the above claim(s) *6-64,68-73,75,78,90,92 and 94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74,76,77,79-89,91 and 93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *35, 20* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment filed 2-7-03 (Paper No. 34) is acknowledged and has been entered.

Claims 6-64 and 68-94 are pending, claims 74-94 having been newly added after the non final rejection was mailed 1-3-01.

Claims 6-64 and 68-73 have been withdrawn from consideration as being drawn to the non-elected invention, as have been newly added claims 75, 78, 90, 92 and 94.

Newly added claims 74, 76-77, 79-89, 91 and 93 are presently under consideration.

In view of said amendment, the art rejections and the 112 first and second paragraph rejections have been withdrawn. However, in view of the newly added claims, new rejections have been applied.

Oath/Declaration

MAINTAINED The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Response to Arguments

Applicant states that a substitute Declaration will be provided in the near future.

Claim Objections

Claims 87 and 88 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 80. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 80-82 are indefinite in their recitation of non-elected material. Specifically said claims encompass claims 75 and 78 which are drawn to a pharmaceutical composition consisting essentially of a nucleic acid.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A) Claims 74, 76-77, 79-81 and 83-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

i) The instant claims 83-88 are drawn to a diagnostic reagent comprising a peptide epitope. The instant specification discloses a method of sequencing pools of peptides that bind HLA-A3, and discloses motifs based on frequency of amino acid residues found at positions 2 and 9 or 10. The instant specification also discloses a peptide (SEQ ID NO:32) that binds HLA-A3 and that is derived from HIV. However, other than said HIV derived peptide, the specification does not disclose which peptides encompassed by the instant claims could be used to diagnose which diseases and conditions. Therefore it would take undue experimentation for one of skill in the art to predict which pharmaceutical compositions comprising the recited genus of peptides, other than SEQ ID NO:32, would be effective in diagnosing any disease or condition, without further guidance and direction from the specification.

ii) The instant claims 74, 76-77 and 79-81 are drawn to a pharmaceutical composition comprising a peptide epitope with a peptide motif of peptides that bind HLA-A3. The instant specification discloses on page 19 that said pharmaceutical compositions are useful for administration to mammals to treat and/or prevent viral diseases or cancer. However, the instant specification does not disclose that any of the recited pharmaceutical compositions is effective in treating and/or preventing cancer or viral diseases. That the efficacy of administered peptides is unpredictable is underscored by Janeway et al (Immunobiology Fourth Edition, page 568-9) who teaches that identifying peptides that bind a class I molecule is only the first step, and that said peptides need to be screened to determine which peptides would be effective in inducing T cell proliferation. In view of the unpredictability of discerning which peptide species from a genus of peptides which have a particular Class I binding motif, will be effective in inducing the proliferation of T cells and thus have the potential to be effective in vivo in treating disease, it would require undue experimentation for one of skill in the art to use the breadth of peptides encompassed by the instant claims in a pharmaceutical composition, without further guidance and direction from the specification.

B) Claims 74, 76-77, 79-81 and 83-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a pharmaceutical composition comprising a peptide epitope comprising about 8 to about 11 amino acids. Engelhard teaches in Current Opinion in Immunology 1994, 6:13-23, that most class I binding peptides are from 8-9 amino acids in llength, and that some are longer. Engelhard does not exemplify class I binding peptides that are less than 8 amino acids in length. Similarly Goldsby et al teaches on pages 170-171 of the Fifth Edition of Immunology that nonamers bind to MHC Class I molecules with a 100 fold greater affinity than those that are shorter. In view of the unpredictability of the binding affinity of peptides shorter than 8 amino acids for Class I molecules, it would require undue experimentation for one of skill to predict which peptides less than 8 amino acids would bind with sufficient affinity to be effective for use in a pharmaceutical composition, without further guidance from the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 74, 76-77, 79-89, 91 and 93 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 97/34617.

'617 teaches a peptide (SEQ ID NO:89) which consists of an amino acid sequence which is an HIV-1 peptide epitope which is identical to that of instantly recited SEQ ID NO:32, (TTLFCASDAK), (see entire patent, including Table 5, Table 9 on pages 38-39), and pharmaceutical compositions thereof (see entire patent including page 20, lines 18-32), and diagnostic reagents thereof (see entire patent including page 32, lines 29-31, and page 33, lines 1-6). Therefore, the instant claims are anticipated by the referenced art.

Conclusion

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
April 18, 2003

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Primary Patent Examiner,
Group 1640